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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/451,643	11/30/1999	Daizhen Gao	C-3169-1-US	9327

7590 05/20/2003

Pharmacia Corporation
Patent Department
800 N. Lindbergh Boulevard
St. Louis, MO 63017

EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	09/451,641	GAO ET AL.
	Examiner	Art Unit
	Susan Tran	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50 and 76-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50, 76-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). ____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Petition under 1.137(b) and Request for Reconsideration filed 01/14/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black EP 0 863 134.

Black teaches a compound useful as a Cox-2 inhibitor for pain relief, fever and inflammation of a variety symptoms disclosed on page 3, lines 29-36. The compound can be administered orally in the form of tablets, troches, lozenges, or capsules (page 4, lines 1-12). The tablets comprising active ingredient in admixture with excipients, *e.g.*, diluents, disintegrants, binding agents, wetting agents, and surfactant (page 4, lines 15-38). The active agent present in an amount of 10 to 250 mg, and carrier material may vary from about 5 to about 95% (page 5, lines 39-58). The dosage can be administered once or twice a day, and will provide effective $T_{1/2}$ over a 24 hours period (page 5, lines 22-27). Example 2 discloses the amount of excipients use in a tablet.

The examiner notes that the reference is silent as to the teaching of celecoxib. However, it is the position of the examiner that celecoxib is a known selective Cox-2

inhibitor, and therefore, it would have been prima facie obvious for one of the ordinary skill in this art to, by routine experimentation determine suitable Cox-2 inhibitor to treat cyclooxygenase-2 mediated diseases. The expected result would be a suitable Cox-2 inhibitor composition having long half-life useful for the treatment of cyclooxygenase-2 diseases.

Claims 76-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black, and Plachetka et al., and Liversidge et al. US 5,552,160.

Black and Plachetka are relied upon for the reasons stated above. The references are silent as to the teaching of the process of reducing the particle size.

Liversidge teaches composition comprising NSAID, and process of preparing same (see abstract). The NSAID particle is preferably having size less than 100 μm (column 4, lines 45-54). The process of reducing the particle size is by milling using suitable mills includes high shear media mill (column 4, lines 55 through column 7, lines 1-16). Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare the composition of Black and Plachetka, using the process of Liversidge, because it is well known in pharmaceutical art that dissolution rate can be improved by decreasing particle size.

The examiner notes that the cited references do not teach the cooling using liquid nitrogen. However, it is also well known in pharmaceutical art to use liquid nitrogen to cool any hot mixture to obtain room temperature.

Response to Arguments

Applicant's arguments filed 01/14/03 have been fully considered but they are not persuasive.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black EP 0 863 134.

Applicant argues that there is no suggestion, either in Black or in generally available knowledge to modify the reference. Although applicant admits that celecoxib is a compound having similar utility (a selective COX-2 inhibitory drug) to Black's compound, applicant alleges that Black fails to teach the claimed compound. In response to applicant's argument that there is no suggestion to modify the reference, the examiner recognizes that obviousness can only be established by modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the reference itself or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Black teaches a compound useful as a Cox-2 inhibitor in the form of powders, granules, tablets, troches, suspensions, or emulsions for pain relief, fever and inflammation. The composition comprises carriers, diluents, excipients, surfactant, dispersing agent, and wetting agent in an amount falls within the claimed ranges. Because Cox-2 inhibitor is poorly water soluble drug, therefore, wetting agent and/or dispersing agent are added to increase solubility. In response to applicant's argument that the reference fails to show certain feature of

applicant's invention, it is noted that the feature upon which applicant relies (i.e., claimed celecoxib compound) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Black does not teach the property, namely high relative bioavailability by comparison with an orally administered solution of the drug, that makes the present invention so desirable. Absent of showing evidence on the contrary, although Black is silent as to the bioavailability, Black recognizes that COX-2 inhibitory drug is poorly soluble, therefore, Black suggests the use of dispersing agent, as well as, wetting agent in his solid oral composition. Applicant specification page 48, lines 15-16 discloses, co-precipitating the celecoxib with a wetting agent (composition C) increased the bioavailability of celecoxib. Thus, it is the position of the examiner that Black's composition would also have high bioavailability. Applicant has not provide any data showing that Black's composition does not exhibit a relative bioavailability by comparison to the present invention. It would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable relative bioavailability of an oral dosage form, because COX-2 inhibitor is a well known drug in the pharmaceutical art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600